

AMENDED IN ASSEMBLY APRIL 17, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2911

Introduced by Assembly Member Nunez
(Coauthor: Senator Perata)

February 24, 2006

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to pharmacy assistance, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2911, as amended, Nunez. California Discount Prescription Drug Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Discount Prescription Drug Program within the department. The bill would require the department to negotiate drug discount agreements with drug manufacturers and pursue manufacturer rebate agreements for drugs in each therapeutic category. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to participate in the program. The bill would establish eligibility criteria and application procedures for eligible Californians to participate in the program. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program.

The bill would establish the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would continuously appropriate the fund to the department for purposes of the program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature hereby finds and declares all of
- 2 the following:
- 3 (a) The people of California find that affordability is critical in
- 4 providing access to prescription drugs for California residents,
- 5 particularly the uninsured and those with inadequate insurance.
- 6 (b) The California Discount Prescription Drug Program is
- 7 enacted by the people to enable the state to take steps to make
- 8 prescription drugs more affordable for qualified California
- 9 residents, thereby increasing the overall health of California
- 10 residents, promoting healthy communities, and protecting the
- 11 public health and welfare.
- 12 (c) It is not the intent of the state to discourage employers
- 13 from offering or paying for prescription drug benefits for their
- 14 employees or to replace employer-sponsored prescription drug
- 15 benefit plans that provide benefits comparable to those made
- 16 available to qualified California residents under this program.
- 17 SEC. 2. Division 112 (commencing with Section 130500) is
- 18 added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA DISCOUNT
PRESCRIPTION DRUG PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the California Discount Prescription Drug Program.

130501. For purposes of this division, the following definitions shall apply:

(a) "Department" means the State Department of Health Services.

(b) "Eligible Californian" means any one or more of the following:

(1) A resident of the state whose total unreimbursed medical expenses equal 10 percent or more of family income and whose family income does not exceed 200 percent of the median family income in the state.

(2) An individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare *or by an individual's private drug plan* or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.

(3) A resident of the state who has a family income equal to or less than 350 percent of the federal poverty guidelines and does not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program, the Healthy Families Program, or other program funded by the state.

(4) For purposes of this subdivision, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(c) "Fund" means the California Discount Prescription Drug Program Fund.

(d) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(e) "Manufacturer's rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(f) “Multiple-source drug” means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.

(g) “National Drug Code” or “NDC” means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(h) “Participating manufacturer” means a drug manufacturer that has contracted with the department to provide an individual drug or group of drugs for the program.

(i) “Participating pharmacy” means a pharmacy that has executed a pharmacy provider agreement with the department for this program.

(j) “Pharmacy contract rate” means the negotiated per prescription reimbursement rate for drugs dispensed to eligible Californians.

(k) “Prescription drug” means any drug that bears the legend: “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(l) “Private discount drug program” means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

(m) “Program” means the California Discount Prescription Drug Program.

(n) “Therapeutic category” means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130502. The California Discount Prescription Drug Program is hereby established within the State Department of Health Services to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for *eligible* Californians. The purpose of the program is to reduce prescription drug prices and improve the quality of health care for eligible Californians.

CHAPTER 2. PRESCRIPTION DRUG DISCOUNTS

130505. (a) The amount a participating, eligible Californian pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the ~~drug's manufacturer and the state's share of the discount.~~ *drug's manufacturer.*

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130506. (a) The department shall negotiate drug discount agreements with drug manufacturers to provide for discounts for prescription drugs purchased through this program. The department shall pursue manufacturer rebate agreements for drugs in each therapeutic category.

(b) The department shall attempt to obtain discounts for eligible Californians that on an average equal or exceed ~~50 percent of the list price, or that average 80 percent of the lowest~~ *Medicaid best price or a price that averages 80 percent of the lowest* wholesale acquisition cost price, for a drug published by a wholesaler in the state generally available to the retail class of trade in the state.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(d) The drug rebate agreements negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by program participants.

(e) (1) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(2) Any drug manufacturer may participate in the program.

130507. (a) The department shall attempt to negotiate drug discount agreements with drug manufacturers for a period not to exceed three years from January 1, 2007. At that time, the department shall make a determination as to whether:

1 (1) The number and type of drugs available through the
2 program is sufficient to give eligible Californians a formulary
3 comparable to that provided to Medi-Cal beneficiaries or, if this
4 information is available to the department, a formulary
5 comparable to that provided to CalPERS enrollees.

6 (2) The discounts for the drugs on an average equal or exceed
7 the threshold in subdivision (b) of Section 130506.

8 (3) Manufacturer participation has been sufficient to provide
9 discounts on a range of drugs consistent with this section.

10 (b) If the department determines that any one of the thresholds
11 in this section is not met, then the department shall implement
12 Sections 130508 and 130509.

13 130508. (a) Consistent with federal law, the department shall
14 seek to contract for that result in a net price comparable to or
15 lower than the Medicaid best price for drugs covered by the
16 California Discount Prescription Drug Program. ~~The department~~
17 ~~shall also seek to contract a net price comparable to or lower than~~
18 ~~the price for prescription drugs provided to the federal~~
19 ~~government.~~

20 ~~(b) The department shall seek a state plan amendment that~~
21 ~~maximizes the number of eligible Californians able to receive~~
22 ~~discounts consistent with this section.~~

23 ~~(c) If the federal Centers for Medicare and Medicaid Services~~
24 ~~deny approval of a state plan amendment or federal waiver for~~
25 ~~any Californians eligible under state law for drug discounts, then~~
26 ~~the department shall continue to operate a discount drug program~~
27 ~~for these persons consistent with Section 130507. To the~~

28 ~~(b) To the~~ maximum extent possible, the department shall
29 assure that enrollment and other administrative actions are
30 seamless to all eligible Californians, whether the eligible
31 Californian is enrolled in a program administered consistent with
32 this section or with Section 130507.

33 130509. (a) ~~Subject to this section, the department shall not~~
34 ~~enter into a new contract or extend an existing contract with a~~
35 ~~drug manufacturer for the Medi-Cal program if the drug~~
36 ~~manufacturer does not provide to the California Discount~~
37 ~~Prescription Drug Program a rate comparable to or lower than the~~
38 ~~Medicaid best price. This prohibition shall not apply to a drug for~~
39 ~~which there is no therapeutic equivalent.~~

1 ~~(b)~~ To the extent permitted by federal law, the department may
2 require prior authorization in the Medi-Cal program for any drug
3 of a manufacturer that fails to agree to a price comparable to or
4 lower than the Medi-Cal best price for prescription drugs
5 purchased under this division.

6 ~~(e) If a contract with a manufacturer is prohibited by~~
7 ~~subdivision (a) or if~~

8 *(b)* If prior authorization is required for a drug pursuant to this
9 section, a Medi-Cal beneficiary shall not be denied the continued
10 use of a drug that is part of a prescribed therapy until that drug is
11 no longer prescribed for that beneficiary's therapy. The
12 department shall approve or deny requests for prior authorization
13 necessitated by this section as required by state or federal law.

14 ~~(d)~~

15 *(c)* This section shall be implemented in a manner consistent
16 with federal law.

17 130510. The names of manufacturers that do or do not enter
18 into rebate agreements with the department pursuant to this
19 division shall be public information, ~~shall be released to the~~
20 ~~public~~, and shall be posted on the department's Internet Web site
21 at the time when the rebate agreements are reached, commencing
22 within six months after the initial implementation date of this
23 article and updated on the first of each month thereafter.

24 130511. (a) Each drug rebate agreement shall do all of the
25 following:

26 (1) Specify which of the manufacturer's drugs are included in
27 the agreement.

28 (2) Permit the department to remove a drug from the
29 agreement if there is a dispute over the drug's utilization.

30 (3) Require the manufacturer to make a rebate payment to the
31 department for each drug specified under paragraph (1)
32 dispensed to a program participant.

33 (4) Require the manufacturer to make the rebate payments to
34 the department on at least a quarterly basis.

35 (5) Require the manufacturer to provide, upon the request of
36 the department, documentation to validate the rebate.

37 (6) Permit a manufacturer to audit claims for the drugs the
38 manufacturer provides under the program. Claims information
39 provided to manufacturers shall comply with all federal and state

1 privacy laws that protect a program participant's health
2 information.

3 (b) The department may collect prospective rebates from
4 manufacturers for payment to pharmacies. The amount of the
5 prospective rebate shall be specified in the drug rebate
6 agreements.

7 (c) (1) Manufacturers shall calculate and pay interest on late
8 or unpaid rebates. The interest shall not apply to any prior period
9 adjustments of unit rebate amounts or department utilization
10 adjustments.

11 (2) For state rebate payments, manufacturers shall calculate
12 and pay interest on late or unpaid rebates for quarters that begin
13 on or after January 1, 2007.

14 (d) Interest required by subdivision (c) shall begin accruing 38
15 calendar days from the date of mailing of the invoice, including
16 supporting utilization data sent to the manufacturer. Interest shall
17 continue to accrue until the date of mailing of the manufacturer's
18 payment. Interest rates and calculations for purposes of this
19 section shall be at ____ percent.

20 (e) A participating manufacturer shall clearly identify all
21 rebates, interest, and other payments, and payment transmittal
22 forms for the program, in a manner designated by the
23 department.

24 130512. (a) The department shall generate a monthly report
25 that, at a minimum, provides all of the following:

26 (1) Drug utilization information.

27 (2) Amounts paid to pharmacies.

28 (3) Amounts of rebates collected from manufacturers.

29 (4) A summary of the problems or complaints reported
30 regarding the program.

31 (b) Information provided in paragraphs (1), (2), and (3) of
32 subdivision (a) shall be at the national drug code level.

33 130513. (a) The department shall establish and maintain a
34 claims processing system that complies with all of the following
35 requirements:

36 (1) Charges a price that meets the requirements of this
37 division.

38 (2) Provides the pharmacy with the dollar amount of the
39 discount to be returned to the pharmacy.

1 (3) Provides drug utilization review warnings to pharmacies
2 consistent with the drug utilization review standards provided in
3 federal law.

4 (b) The department shall pay a participating pharmacy the
5 discount provided to program participants pursuant to this
6 division by a date that is not later than two weeks after the claim
7 is received.

8 (c) The department shall develop a mechanism for the
9 program participants to report problems or complaints.

10
11 CHAPTER 3. APPLICATION, ENROLLMENT, AND OUTREACH
12

13 130520. (a) The department shall develop an application and
14 reapplication form for the determination of a resident's eligibility
15 for the program. An applicant, or a guardian or custodian of an
16 applicant, may apply or reapply on behalf of the applicant and
17 the applicant's spouse and children.

18 (b) The application shall, at a minimum, do all of the
19 following:

20 (1) Specify the information that an applicant or the applicant's
21 representative must include in the application.

22 (2) Require that the applicant, or the applicant's guardian or
23 custodian, attest that the information provided in the application
24 is accurate to the best knowledge and belief of the applicant or
25 the applicant's guardian or custodian.

26 (3) Specify that the application fee due upon submission of the
27 applicable form is ten dollars (\$10) *annually*.

28 (c) In assessing the income requirement for eligibility, the
29 department shall use the income information reported on the
30 application and not require additional documentation.

31 (d) An application may be completed at any pharmacy,
32 physician office, or clinic participating in the program through an
33 Internet Web site or call center staffed by trained operators
34 approved by the department. A pharmacy, physician's office,
35 clinic, or nonprofit community organization that completes the
36 application shall keep the application fee as reimbursement for its
37 processing costs. If it is determined that the applicant is already
38 enrolled in the program, the fee shall be returned to the applicant
39 and the applicant shall be informed of his or her current status as
40 a program participant.

1 (e) The department shall utilize a secure electronic application
2 process that can be used by a pharmacy, physician's office, or
3 clinic, by an Internet Web site, by a call center staffed by trained
4 operators, by a nonprofit community organization, or through the
5 third-party vendor to enroll applicants in the program.

6 (f) During the department's normal working hours, the
7 department shall make a determination of eligibility within 24
8 hours of receipt by the program of a completed application. The
9 department shall mail the program participant an identification
10 card no later than seven days after eligibility has been
11 determined.

12 (g) For applications submitted through a pharmacy, the
13 department may issue a participant identification number for
14 eligible applicants to the pharmacy for immediate access to the
15 California Discount Prescription Drug Program.

16 (h) Any program participant that has been determined to be
17 eligible shall be enrolled for 12 months, ~~which ever occurs first~~
18 or until the program participant notifies the department of an
19 intent to end enrollment.

20 (i) The department shall notify a program participant of
21 termination of enrollment 30 days prior to the termination. ~~A~~
22 ~~program participant shall remain enrolled in the program until the~~
23 ~~participant notifies the department that the participant no longer~~
24 ~~meets the eligibility criteria.~~

25 (j) A person shall be required to apply pursuant to this section
26 for each 12-month period of eligibility.

27 130521. (a) The department may conduct an outreach
28 program to inform California residents of their opportunity to
29 participate in the program. The department shall coordinate
30 outreach activities with the California Department of Aging and
31 other state and local agencies, and nonprofit organizations that
32 serve residents who may be eligible for the program. No outreach
33 material shall contain the name or likeness of a drug.

34 (b) The department may accept on behalf of the state any gift,
35 bequest, or donation of outreach services or materials to inform
36 residents about the program. The name of the organization
37 sponsoring the materials shall in no way appear on the material
38 but shall be reported to the public and the Legislature as
39 otherwise provided by law.

1 130522. (a) A drug dispensed pursuant to prescription,
2 including a drug dispensed without charge to the consumer, shall
3 be accompanied by the California Discount Prescription Drug
4 Program participation information in a manner approved by the
5 department and as permitted by law.

6 (b) The information shall include advice to consult a health
7 care provider or pharmacist about access to drugs at lower prices.

8 (c) The requirements of this section may be met by the
9 distribution of a separate information form that is approved by, or
10 produced and distributed by, the department.

11
12 CHAPTER 4. PHARMACEUTICAL MANUFACTURER PATIENT
13 ASSISTANCE PROGRAMS
14

15 130530. (a) The department shall encourage a participating
16 manufacturer to maintain those private discount drug programs
17 that are comparable to or more extensive than those provided
18 prior to the enactment of this division. To the extent possible, the
19 department shall encourage a participating manufacturer to
20 simplify the application and eligibility processes for its private
21 discount drug program.

22 (b) The department shall execute agreements with drug
23 manufacturers and other private patient assistance programs to
24 provide a single point of entry for eligibility determination and
25 claims processing for drugs available through those programs.

26 (c) The department shall develop a system to provide a
27 program participant under this division with the best discounts on
28 prescription drugs that are available to the participant through
29 this program or through a drug manufacturer or other private
30 patient assistance program.

31 (d) (1) The department may require an applicant to provide
32 additional information to determine the applicant's eligibility for
33 other discount card and patient assistance programs.

34 (2) The department shall not require an applicant to participate
35 in a drug manufacturer patient assistance program or to disclose
36 information that would determine the applicant's eligibility to
37 participate in a drug manufacturer patient assistance program in
38 order to participate in the California Discount Prescription Drug
39 Program.

(e) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(f) The California Discount Prescription Drug Program card issued pursuant to this division shall serve as a single point of entry for drugs available pursuant to subdivision (a), and shall meet all legal requirements for a health benefit card.

CHAPTER 5. ADMINISTRATION

130540. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130541. To implement the program, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. Drug rebate contracts negotiated by a third party shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or program participants.

130542. (a) The department shall deposit all payments the department receives pursuant to this division into the California Discount Prescription Drug Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to this division and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General

1 Fund. The fund shall also contain any interest accrued on moneys
2 in the fund.

3 130543. (a) (1) The director may adopt regulations as are
4 necessary for the initial implementation of this division. The
5 adoption, amendment, repeal, or readoption of a regulation
6 authorized by this section is deemed to be necessary for the
7 immediate preservation of the public peace, health and safety, or
8 general welfare, for purposes of Sections 11346.1 and 11349.6 of
9 the Government Code, and the department is hereby exempted
10 from the requirement that it describe specific facts showing the
11 need for immediate action.

12 (b) As an alternative to the adoption of regulations pursuant to
13 subdivision (a), and notwithstanding Chapter 3.5 (commencing
14 with Section 11340) of Part 1 of Division 3 of Title 2 of the
15 Government Code, the director may implement this division, in
16 whole or in part, by means of a provider bulletin or other similar
17 instructions, without taking regulatory action, provided that no
18 bulletin or other similar instructions shall remain in effect after
19 July 31, 2007. It is the intent that regulations adopted pursuant to
20 this subdivision shall be in place on or before July 31, 2007.

21 SEC. 3. No reimbursement is required by this act pursuant to
22 Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the
26 penalty for a crime or infraction, within the meaning of Section
27 17556 of the Government Code, or changes the definition of a
28 crime within the meaning of Section 6 of Article XIII B of the
29 California Constitution.